5/14/98

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
T1743M

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

April 10, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our ref: 2953212

## WARNING LETTER

Naum Pinkhasik, President
International Technology Concepts, Inc.
11501 Dublin Blvd., #101
Dublin, CA 94568

Dear Mr. Pinkhasik:

An inspection was conducted of your firm located in Dublin, California on February 9 and 10, 1998. At that time the investigator determined that your firm manufactures and distributes intraoral cameras and accessories. These products are devices as defined by Section 210(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are misbranded within the meaning of Section 502(o) of the Act in that they were manufactured in an establishment not duly registered under Section 510, were not included in a list required by Section 510(j), and a notice or other information respecting the devices was not provided to the FDA as required by Section 510(k).

San Francisco District acknowledges that as a result of a recent import detention of the camera subassemblies, your company has submitted registration and listing information to FDA which is now being processed. Annual renewal of this initial registration will be required if your firm continues to manufacture the intraoral cameras and accessories in Dublin, California.

Between August 1, 1997 and February 10, 1998 your company manufactured and distributed approximately [redacted] SpectraVu 100 and 200 cameras and accessories. Our inspection showed

that your company has not made a 510(k) submission for any of these products. We understand that you have agreed to cease distribution of these devices from your facility pending 510(k) clearance.

Additionally, FDA believes that your intraoral cameras and accessories are adulterated under Section 501(f)(1)(B) of the Act because they are considered to be Class III devices under Section 513(f), which are not exempt under 520(g), and are required to have in effect an approved application for premarket approval, and no such approval is in effect for them.

You should take prompt action to correct these deviations from the Act. Failure to take prompt corrective action may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, or the specific steps you have taken to correct the noted violations. Please include in your response an explanation of the steps being taken to identify and correct any underlying problems which will assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the date on which the corrections will be completed.

Your response should be sent to Andrea P. Scott, Compliance Officer, Food and Drug Administration, 96 North Third St., Suite 325, San Jose, CA 95112.

You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1(800)638-2041 or through the Internet at http://www.fda.gov.

Sincerely,

Charles D. Moss
Acting District Director

for Patricia C. Ziobro
District Director
San Francisco District